

Serial No. 09/888,837
Docket No. MICRODOSE 00.01
Amendment B under Rule 116

REMARKS

Claim 1 has been amended to incorporate the limitations of claim 2, which has been cancelled. Pursuant to 37 CFR § 1.121 a marked copy of the amended claim showing the changes made therein accompanies this Amendment.

Turning to the art rejections, and considering first the rejection of claims 1, 8, 13, 14 and 15 as anticipated by Eisele et al., as noted *supra*, claim 1 has been amended to incorporate the limitations of claim 2. Thus, the §102 rejection is rendered moot.

The primary reference Eisele et al., '663, is fundamentally different from Applicant's claimed invention. Eisele et al. features a rigid disk carrying a plurality of spaced blister packs. Applicant's independent claim 1, and the several claims dependent thereon, require an elongate flexible tape. An elongate flexible tape is fundamentally different from a rigid disk, and provides significant advantages, i.e., in terms of compactness since a flexible elongate tape may be wound into a tight package. Thus, Eisele et al.'s carrier disk is limited in the number of doses that can be carried without becoming too bulky.

Moreover, as pointed out in Amendment A, which is incorporated by reference, the primary reference Eisele et al. teaches a blister pack for a dry powdered inhaler where shear layers of the blisters are pierced, releasing medication into the inhaler (col. 3, lines 35-40). In Eisele et al., the disk must be oriented so that the shear layer is located on the bottom of the blister pack (col. 3, lines 10-12; Figures 5-7), whereby the contents are released and fall under the influence of gravity to the inside of the inhaler where the contents are mixed with air. Thus, Eisele et al.'s dry powder inhaler delivery system, which relies on gravity for dumping the

HAYES SOLOWAY P.C.
130 W. CUSHING ST.
TUCSON, AZ 85701
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
ANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567

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contents of the blister, is position dependent. It cannot be turned upside down, or sideways, and may not work particularly well with a patient in a reclining position. Applicant's claimed invention, on the other hand, is for use with an inhalation therapy inhaler equipped with a vibratory de-aggregator. Thus, Applicant's claimed blister pack is not position dependent, and is designed for mating with a vibratory de-aggregator whereby the blister pack contents will be forcibly ejected from the pack, i.e. by the vibratory de-aggregator. (1)

In the rejection, the Examiner argues that in Eisele et al. the bottom portion is the sheer layer 56 defining a top portion 54, with 56 extending between spaced top portions 54 (Figures 2, 3, 4 and 5). But, in Eisele et al. the shear layer 56 is designed to be pierced to allow the contents of the blister to empty. Thus, in Eisele et al. the shear layer 56 is incapable of coupling with a vibratory de-aggregator.

In the rejection, the Examiner takes the position that the claim language "spaced areas for interfacing and coupling with the inhaler vibratory de-aggregator" is simply recitation of intended use, and refuses to consider same. The Examiner is in error. Applicant respectfully submits providing spaced interface areas on an elongated flexible tape as required by independent claim 1 is a structural feature not found in Eisele et al. As mentioned *supra*, Eisele et al. teaches a rigid disk. Thus, if vibratory energy were imparted to a selected area of Eisele et al., the vibratory energy would be dissipated around the entire disk. Applicant's claimed invention, on the other hand, specifies an elongate flexible tape having spaced areas. Thus, vibratory energy imparted to one area of the flexible tape will be confined essentially to that area due to the flexible nature of the tape.

HAYES SOLOWAY P.C.
130 W. CUSHING ST.
TUCSON, AZ 85701
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FAX. 520.882.7643

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Turning to the specific §103 rejections, and considering first the combination of Eisele et al. and Abrams et al., i.e., as applied to claim 2 which has been incorporated into claim 1, Eisele et al. and Abrams et al. are fundamentally different. Eisele et al. is a rigid disk, and as discussed above, relies on gravity. Abrams et al. has been cited as teaching an elongate flexible tape, and is acknowledged as so teaching. However, it is submitted there is no possible reason why one skilled in the art would consider modifying Eisele et al. to incorporate an elongate flexible tape as taught by Abrams et al. The two technologies are fundamentally different, and clearly, a flexible tape cannot function in Eisele et al.'s inhaler any more than Eisele et al.'s rigid disk can function in a vibratory inhaler as required in Applicant's claims. Thus, it is submitted the Examiner is applying impermissible hindsight and is applying the teachings of the present invention to the prior art to make out a case for obviousness in attempting to combine Eisele et al. and Abram's et al.

Turning to the remaining obviousness rejections, Eisele et al. '237 is similar to the Eisele et al. '663 primary reference, and relies on gravity to dump the contents to a staging area under the blister pack. Pera, which is cited as teaching dispensing anti-oxidant vitamins, shows no specific blister pack structure. Hendricks, which is cited as teaching a dry powder inhaler for a hormone or steroid is quite different. Hendricks discloses a slidable dosing tray for dispensing medication from a storage chamber into an air passageway. Finally, Shyjan, which has been cited as teaching a blister pack containing a bio-active material, also fails to teach or suggest any particular blister pack structure.

Accordingly, since the several secondary references alone, or in combination with Eisele et al. '663, fail to teach or suggest the blister pack as claimed in claim 1, it is submitted that no

HAYES SOLOWAY P.C.
130 W. CUSHING ST.
TUCSON, AZ 85701
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
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combination of the art cited by the Examiner reasonably could be said to achieve or render obvious claim 1, or any of the claims dependent thereon. Thus, the several rejections of the claims as obvious from the art is likewise in error.

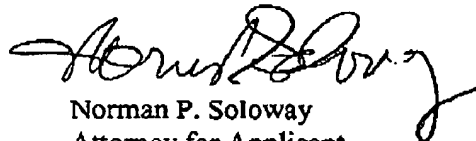
Accordingly, claims 3-5 and 8-15 are patentable over the art of record for the same reasons above adduced relative to claim 1, as well as for their own additional limitations.

Having dealt with all of the objections raised by the Examiner, the Application is believed to be in order for allowance.

The foregoing Amendment merely combines claims 1 and 2, which have already been considered by the Examiner. Accordingly, no new issues have been raised which would require further search. Thus, it is believed that the foregoing Amendment should be entered as a matter of right.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our deposit account number 08-1391.

Respectfully submitted,

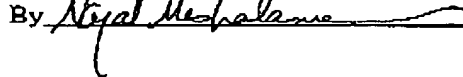


Norman P. Soloway
Attorney for Applicant
Registration No. 24,315

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I hereby certify that this correspondence is being sent via facsimile to EXAMINER NIHIR B. PATEL of the United States Patent and Trademark Office at facsimile number (703) 872-9303, on April 18, 2003 from Tucson, Arizona.

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By 

AYES SOLOWAY P.C.
130 W. CUSHING ST.
TUCSON, AZ 85701
TEL. 520.882.7623
FAX. 520.882.7643

175 CANAL STREET
ANCHESTER, NH 03101
TEL. 603.668.1400
FAX. 603.668.8567

MARKED COPY OF AMENDED CLAIM

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Marked Amended Claim - Amendment B

MARKED AMENDED CLAIM:

1. (Twice Amended) A blister pack for use with inhalation therapy inhalers equipped with a vibratory de-aggregator, comprising a first element comprising an elongate flexible tape having spaced areas for interfacing and coupling with the inhaler vibratory de-aggregator, and a frangible second element overlying the first element and defining a plurality of spaced top crowned areas located over said first element spaced areas, and containing powder or liquid material.